Comments of the American Chemistry Council on CBI Claims for Underlying Data for Health and Safety Studies under TSCA

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EPA Should Accept CBI Claims for Underlying Data for Health and Safety Studies Submitted Under TSCA

EPA should balance the competing interests of public access to health and safety studies submitted under TSCA and protection of data compensation rights of the study submitters. It may do this under section 14 of TSCA by accepting substantiated claims that underlying data qualify for protection from disclosure under section 14(a). Disclosing the final study report while withholding the underlying data would provide the public with key information about the study while protecting the rights of data owners.

1. Legal Framework Allowing Protection of Underlying Data from Disclosure

EPA has discretion under section 14 to disclose the study reports for studies submitted under TSCA and to withhold from public disclosure the data underlying of those study reports that are submitted to EPA or which EPA otherwise obtains.

Subject to certain exceptions, the Freedom of Information Act (FOIA)[1] directs EPA to release to the public upon request the information submitted to it under its various statutes, including TSCA. Exemption 4, however, exempts from this mandatory disclosure obligation "trade secrets and commercial or financial information obtained from a person and privileged or confidential" (CBI).[2] This provision does not prohibit disclosure of such CBI, however.

Section 14(a) of TSCA as amended[3] is a broad reverse-FOIA statutory provision that prohibits EPA from disclosing publicly information qualifying under FOIA exemption 4. Section 14(a) provides in part:

> IN GENERAL.—Except as provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section—
> (1) that is reported to, or otherwise obtained by, the Administrator under this Act; and
> (2) for which the requirements of subsection (c) are met.

Section 14(a) is itself subject to exceptions, however. Among them is section 14(b)(2), which provides in part:

> INFORMATION FROM HEALTH AND SAFETY STUDIES.—Subsection (a) does not prohibit the disclosure of—

[1] 5 U.S.C. § 552.
[2] 5 U.S.C. § 552(b)(4).
[3] Amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), Pub. L. 114-182 (June 22, 2016).

> (A) any health and safety study which is submitted under this Act with respect to—
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> (i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution; or
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> (ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5; and
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> (B) any information reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

The phrase "does not prohibit the disclosure" leaves to EPA the discretion and decision regarding the extent to which it will disclose a health and safety study. TSCA "does not prohibit the disclosure" of a health and safety study containing CBI due to section 14(b)(2). On the other hand, FOIA does not mandate the disclosure of a health and safety study qualifying as CBI due to paragraph (b)(4). The clear implication is that EPA has discretion to decide to what extent it will or will not disclose health and safety studies containing CBI, such as underlying data.

Section 14(b)(5) does not preclude EPA from exercising discretion to withhold underlying data. It provides:

> CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information reported to or otherwise obtained by the Administrator under this Act that is not protected from disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

As noted above, the basis for EPA's discretion would be its judgment in balancing competing interests, not because FOIA exemption 4 applies. EPA has previously exercised similar discretion in its regulations permitting CBI claims for chemical identity in health and safety studies submitted to support a PMN where a robust generic name is provided.[4]

2. The Competing Interests

When EPA exercises its discretion to decide to what extent to disclose a health and safety study, it should consider the competing interests at stake.

a. The Public Interest in Transparency of EPA Decision-Making

The public interest underlying section 14(b)(2) reflects the congressional intent that the basis for EPA's decision-making under TSCA should be transparent. As amended, section 26(i) requires EPA to make its decisions based on the weight of the scientific evidence, and section 26(h) directs EPA to make its decisions in a manner consistent with the best available science. Section 26(j)(4) requires EPA to make available to the public a list of

[4] 40 C.F.R. § 720.85(a)(2), (b)(3).

the studies considered when completing risk evaluations. Collectively, these provisions are advanced by making the health and safety studies on which EPA relies in its decision-making available to the public.

As discussed below, however, the public interest in access to underlying data for submitted studies is limited when balanced against the commercial interest in protecting competitive data from disclosure.

b. The Commercial Interest in Protecting Competitive Data from Disclosure

Congress expressed concern that CBI in health and safety studies not be disclosed. The Senate Report for S. 697 (the Senate version of what became the LCSA) cautioned:

> The Committee expects that EPA will ensure that health and environmental effects information from health and safety studies is disclosed, while appropriately protecting CBI contained within a study.[5]

Sometimes the CBI in a health and safety study to be protected is the specific identity of the chemical substance that is the subject of the study.[6] To make this point, Congress added to an exception to section 14(b)(2) a reference to information that reveals "molecular structures." To ensure that the public would be able to understand studies for which the chemical identity is withheld as CBI, however, Congress in section 14(c)(1)(C) required a CBI claim for a chemical identity to include "a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public."

Sometimes the CBI in a health and safety study to be protected is competitive information, such as "company name or address, financial statistics, and product codes used by a company."[7] In other instances the CBI in a health and safety study to be protected is, instead, the underlying data. EPA interprets "underlying data" to include "medical or health records, individual files, lab notebooks, and daily monitoring records supporting studies."[8] Another term for "underlying data" is "raw data."[9] Sometimes underlying data

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[5] S. Rep. 114-67 (June 18, 2015) at 22.

[6] Prior to enactment of the LCSA, EPA took the position that "[c]hemical identity is part of, or underlying data to, a health and safety study," citing 40 C.F.R. § 716.3 (regulatory definition of "health and safety study"), and thus that confidential chemical identities in a health and safety study submitted under TSCA must be disclosed except as provided in the exception to section 14(b)(2). Industry disagreed with this position, arguing that chemical identities in health and safety studies could be withheld as CBI more broadly. In amending section 14(b), Congress recognized but did not resolve this dispute. See S. Rep. 114-67 at 22.

[7] See 40 C.F.R. § 716.55(a)(4) (allowing study submitters under section 8(d) to omit such information from a study). The provision purports to rely on FOIA exemption 6 for information related to personal privacy, but is instead corporate information. Under the Supreme Court's decision in *FCC v. AT&T, Inc.*, 562 U.S. 397, 408 (2011), however, corporate information is not eligible for exemption 6. The basis for this provision is actually exemption 4. This information is comparable to that excluded from the need for routine substantiation under section 14(c)(2).

[8] 40 C.F.R. § 716.10(a)(4).

[9] The TSCA Good Laboratory Practice (GLP) regulations define "raw data" in 40 C.F.R. § 792.3 as follows: "*Raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the

appears in lengthy appendices to health and safety studies, and at other times underlying data remains in separate files that may or may not be submitted with the study report that is submitted to EPA under TSCA.

Underlying data submitted to EPA under TSCA may qualify as CBI under FOIA exemption 4. While it may not qualify as a trade secret, it is "commercial ... information obtained from a person;" thus, if it is also "confidential," it qualifies for FOIA exemption 4.[10] Commercial information is "confidential" under Exemption 4 if its disclosure is likely "to cause substantial harm to the competitive position of the person from whom the information was obtained."[11] EPA's disclosure of raw data from a study submitted under TSCA, including disclosure to the study submitter's competitors, can cause substantial competitive harm.[12]

Congress recognized in section 4 that health and safety studies can have commercial value to study submitters; thus, underlying data is "commercial information." Section 4(c)(3(A) provides that persons who submit health and safety studies required by EPA may be entitled to "fair and equitable reimbursement" from other companies benefiting by such submission. This provision, like the corresponding provisions in FIFRA, provides a mechanism by which the study owner is owed a measure of data compensation by others who benefit by submission of the study–typically, competitors—by avoiding the need to submit an equivalent study themselves.[13]

Even when the study report is disclosed, the underlying data may be "confidential," i.e., its disclosure may result in substantial competitive harm to the study owner. Often, it is the availability of underlying data that determines whether or not an unpublished study can be used by a competitor to support its notification or registration of a substance overseas without obtaining ownership or citation rights to use such data, depriving the data generator of the value of its investment in the underlying data. A study submitted under TSCA may also need to be submitted to a foreign regulatory agency. If EPA has made the

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result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments."

[10] See, e.g., *Public Citizen Health Research Group v. FDA*, 185 F.3d 898 (D.C. Cir. 1999); *Public Citizen Health Research Group v. FDA*, 704 F.2 1280 (D.C. Cir. 1983).

[11] *See Critical Mass Energy Project v. NRC*, 975 F.2d 871, 878 (D.C.Cir.1992) (en banc) (citing *National Parks*, 498 F.2d at 770).

[12] The raw data of a study not in the public domain qualifies as CBI when that data provides a commercial value to its owner. See, e.g., *Cohen v. Kessler*, No. 95-6140 (D.N.J. Nov. 25, 1996) (drug manufacturer had an express expectation of confidentiality when it submitted raw data to the FDA in support of its application for approval of a new bovine growth hormone and the FDA maintained this data with the strictest confidence; disclosure of raw data is likely to substantially harm company's competitive position because this is the type of information that its competitors would use in order to develop their own version of this bovine growth hormone without incurring the research and development costs). Also see U.S. Department of Justice Guide on FOIA exemption 4 at https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/exemption4_0.pdf

[13] EPA has adopted rules implementing section 4(c)(3)(A) in 40 C.F.R. Part 791.

underlying data from that study public pursuant to section 14(b)(2), competitors would find it easier to use that study—without providing compensation to the original data owner to obtain data access or citation rights—to support their notification or registration of a substance under some foreign counterparts to TSCA.[14]

Any doubts EPA may have to whether underlying data qualifies as CBI may be resolved by review of the substantiation for its CBI claim provided by the study submitter under section 14(c)(3).

3. EPA Should Balance the Competing Interests by Allowing CBI Claims for Underlying Data

a. Section 14 Encourages Balancing of Competing Interests

Congress gave EPA discretion to decide to what extent to require health and safety studies to be disclosed, while protecting the CBI contained within those studies. This reflects the overall interest of Congress in section 14 of balancing the competing interests of transparency in EPA's decision-making and protection of CBI. The Senate Report explained:

> In general, it is the Committee's intent to balance the need for protection from disclosure for information qualifying under the section b(4) exemption of the Freedom of Information Act (FOIA) (i.e., "trade secrets and commercial or financial information obtained from a person and privileged or confidential") with the needs to ensure access to such information under appropriate conditions by those who need it to perform their duties, and to maximize public availability of health and environmental information relating to chemical substances in commerce. Striking a balance between protecting trade secrets and sensitive commercial and financial information and broadening access to information on chemicals is essential to encourage innovation and economic competitiveness within the chemical industry and those industries that use chemistry, while better informing the decisions made about chemicals by different levels of government, companies throughout the supply chain, and the general public.[15]

[14] EPA under FIFRA requires persons citing a study owned by a third party to affirm that they have the study owner's permission to cite the study or have offered to pay data compensation to the study owner. 40 C.F.R. § 152.93(b). Similarly, REACH Article 30 requires SIEF members to pay compensation to other members who own studies needed for registration. Some other counterparts to TSCA do not have such a provision, however. For example, Japan, the Philippines, and Taiwan do not. For them, simply providing a copy of the study, however obtained, may be sufficient and there is no obligation to affirmatively demonstrate that the notifier or registrant has data access privileges. Competitors to the original data generator may be able to obtain full copies of a study from EPA because EPA disclosed it under section 14(b)(2). Without underlying data, however, the study may not be deemed to meet the data requirement.

[15] S. Rep. 114-67 (2015) at 21.

b. The Public Interest in Underlying Data Is Limited Where that Underlying Data Qualifies as CBI

As noted above, the public interest in underlying data is limited in that the human health and environmental results of studies can be made public in a manner to meet the public interest while still protecting the competitive commercial value of underlying data. This may be concluded by EPA's general practice of accepting a study report without submission of underlying data.

Members of the public who may want to review a study on which EPA makes its decisions would presumably have access to the final study report. As described in EPA's GLP regulations, a final report includes extensive information about the study.[16] Many studies submitted to EPA comply with the EPA GLP regulations, which require the Quality Assurance Unit to:

> Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.[17]

Accordingly, members of the public generally have sufficient information to understand the basis for EPA's decision-making if they have access to the final report.

Admittedly, underlying data fits within the definition of "health and safety study." TSCA defines "health and safety" to include "underlying information,"[18] and EPA has defined "health and safety study" to include "underlying data."[19] The section 4 regulations, the section 8(d) regulations, and the PMN regulations require manufacturers to submit health and safety studies to EPA under some circumstances. Nevertheless, it is noteworthy than none of these regulations routinely requires study submitters to submit underlying data along with a final report. This is a clear indication that the final report communicates sufficient information about the potential health and environmental effects to the public when a company has submitted health and safety studies in which it has a commercial interest in protecting.[20]

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[16] 40 C.F.R. § 792.185(a). All test rules and testing consent orders include a requirement to comply with the EPA GLPs, including this provision. Several significant new use rules provide that study reports must include the contents specified in that regulation. 40 C.F.R. §§ 721.537, 721.2122, 721.2584, 721.9928.
[17] 40 C.F.R. § 792.35(b)(6).
[18] TSCA § 3(8).
[19] 40 C.F.R. §§ 716.3, 720.3(k), 725.3.
[20] ACC believes that making a final study report publicly available where the underlying data is CBI would comport with EPA's recent proposal regarding Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768 (April 30, 2018). In addition, where EPA relies on studies where the underlying data is CBI, EPA can access that underlying to confirm the methods, models, and approaches are based on validated procedures, accessible data, etc. If need be, EPA could contract with an independent third-party science reviewer to confirm those findings, although ACC believes this would likely be necessary only in unusual circumstances. EPA might also consider an approach followed under FIFRA where Data Evaluation Records of studies are made publicly available, but not the full study. See, e.g., https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/010501/010501-050.pdf

The section 4 GLP regulations require underlying data to be archived,[21] but the testing requirements only call for submission of a final study report[22] and reference to where the raw data are located.[23] EPA's FIFRA GLPs have a corresponding provision.[24] EPA does not routinely require persons subject to a section 4 testing requirement to submit underling data along with a final report.

The section 8(d) regulations state:

> In general, health and safety studies, as defined in § 716.3, on any substance or listed mixture listed in § 716.120, that are unpublished are reportable, i.e., must be submitted or listed. However, this requirement has limitations according to the nature of the material studied, so that: ...
> (4) **Underlying data**, such as medical or health records, individual files, lab notebooks, and daily monitoring records supporting studies **do not have to be submitted** initially. EPA may request underlying data later under § 716.40.[25]

Similarly, while the PMN regulations require submission of health and safety studies,[26] EPA does not require submission of underlying data, saying:

> The data may be submitted in aggregate or summary form; underlying data, such as individual measurements, are not required.[27]

Instead, EPA concluded that a study report will be sufficient:

> If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.[28]

c. Balancing the Competing Interests Favors Protection of Private Competitive Interests

EPA balanced the public and private interests in disclosure or non-disclosure of chemical identities in health and safety studies submitted to support PMNs, concluding that the private interest outweighed the public interest where the study submitter provided a sufficiently robust generic name.[29] Similarly, EPA should balance the public and private interests in disclosure or non-disclosure of underlying data submitted with studies where

[21] 40 C.F.R. § 792.33(f) (study director must transfer all raw data to archives by the close of the study).
[22] See, e.g., 40 C.F.R. §§ 799.5085(i), 799.5087(i), 799.5089(i).
[23] See, e.g., 40 C.F.R. §§ 795.120(e)(13), 797.1600(e)(12).
[24] 40 C.F.R. § 160.185.
[25] 40 C.F.R. § 716.10(a)(4) (emphasis added).
[26] 40 C.F.R. § 720.50.
[27] 48 Fed. Reg. 41132, 41136 (Sept. 13, 1993).
[28] 40 C.F.R. § 720.50(a)(3)(i).
[29] 40 C.F.R. § 720.85(a)(2), (b)(3); 48 Fed. Reg. 21722, 21739-40 (May 13, 1983).

the study submitter provides a final report which discusses most or all of the information called for by the TSCA GLP regulations and substantiates the CBI claim.

In adopting the section 8(d) exemption for underlying data, EPA explained:

> The final requirements represent the Agency's effort to reduce the burden of the rule while still obtaining the most useful studies for our assessments. EPA received many good comments that allowed the Agency to identify the studies that were most burdensome to submit and least useful for its assessments Therefore, the Agency has added to the exemptions originally proposed. The final rule has the following overall exemptions: ... (7) underlying data such as medical records, monitoring data, and lab notebooks (unless the EPA requests the data later, by personal letter).[30]

In its words, EPA considers underlying data to be "least useful for its assessments." EPA reserved the possibility that it might need underlying data, in which case it could request the underlying data by letter, facility archive inspection/audit, or, potentially, by subpoena.[31] In practice, however, EPA has rarely, if ever, requested underlying data. This long-time experience is strong evidence that, generally, the scientific need for underlying data is low for studies conducted according to GLP regulations. This suggests that the public interest in having access to underlying data for health and safety studies where a final report of a GLP study is provided is also low.

In contrast, the private interest in preserving the compensability of underlying data for studies when submitted under foreign counterparts to TSCA is high. Underlying data can qualify as CBI, and Congress put a premium on preserving CBI in health and safety studies.

EPA should weigh the competing interests and conclude that it should not disclose underlying data submitted or otherwise obtained under TSCA where the study submitter can substantiate its CBI claim and it provides a study report.

[30] 47 Fed. Reg. 38780, 38781 (Sept. 2, 1982).
[31] See 40 C.F.R. § 716.40.